REMARKS

An interview with the Examiner and her supervisor was held on November 10, 2009. Applicants first wish to thank the Examiners for their consideration and time given over to the interview, which was very helpful in advancing the prosecution of this application.

Substance of the Interview

In the interview, the nature of the invention and the features of it that distinguish the invention from the prior art were discussed. The inventor presented a slide show, and the Examiner had asked that copies of the slides be made of record. Accordingly, a copy of the slides presented is appended hereto.

Also discussed in the interview were some issued identified by the Examiner relating to questions of support for various terms in the claims filed October 23, 2009.

In a telephone conversation on January 27, 2010, the Examiner raised a further concern about support in the specification for the features of the invention recited in claim 67, part a)(ii). The Examiner is directed to the disclosure at page 10, lines 5-12.

Amendments to the claims

The claims have been amended herein to address various questions about support for the claim terms or relating to problems of indefiniteness identified during the interview of November 10. Thus:

- the typographical error in claim 67 ("amorphous" at part c)) is corrected;

- the phrase "lower than 0.12 w/w" is amended to include a lower limit on water content in step a2) - support for this amended range stated is found in the specification at least in the working examples 1-4, in which water content of from 0.08 to 0.12% is demonstrated;

- the phrase "free of ethanol" is amended to recite "from which alcoholic solvents have been removed - support for this amendment is found at page 12, lines 8-24, and 31;

- the "preferably" range in part a)(ii) of claim 67 has been deleted and the recitations are armended conform them to the disclosure in the specification.

Applicants have made some additional amendments for purposes of improving the clarity of the claim language, and support for them is found in the specification as follows:

- "pharmaceutical composition" – original claims 38 and 39;

- "tartaric acid" - page 18, line 24;

- "1 to (100 mg/ml)" – page 16, line 16;

- "0.22 to 0.45 microns" – page 17, lines 11-12;

- recitations relating to "intended use" of some ingredients have been deleted.

New claims 80-84 were briefly discussed in the Interview. The Examiner agreed to consider these claims when they were formally presented in an Amendment.

Distinction of the invention from the prior art

As has been discussed in the prosecution to date, the present invention is distinguished from the prior art at least by the use of anhydrous docetaxel and lack of alcohols in the final composition. These features prevent hydrolysis and rearrangements of the docetaxel leading to degradation. None of the references of record describe or suggest that the docetaxel used should be anhydrous or free of alcohols, much less that both of these should be true.

In the interview, the Examiner raised a concern that one of the cited references utilizes a solution of methanol, and thus a composition "free of ethanol" is obtained. However, the present compositions are described as pharmaceutical compositions. The use of methanol in pharmaceutical compositions is prohibited and therefore the claims are free of this reference. In any event, the presently amended claims recite that the composition is one from which "alcoholic solvents" have been removed.

A reference by Kraemer (not of record as of 11/10) is included in an IDS filed with this Supplemental Amendment. Although Kraemer describes docetaxel "free from water", Kraemer does not describe or suggest the absence of alcohols from the composition. Furthermore, at the time of the Kraemer reference, ethanol was commonly used in compositions of docetaxel. Kraemer et al. reference the Rhone-Poulenc formulation (reference 3), which was known to contain ethanol. In this regard, the Examiner should note that at the time Kraemer et al. performed their experiments and published, i.e. around July 2000, Rhone Poulenc Rorer (now Sanofi-Aventis) was the only company that produced and marketed docetaxel compositions. The marketed composition at that time was TAXOTERE® and in its FDA registry the patent documents US 4,814,470, US 5,438,072, US 5,403,858, US 5,698,582, US 5,714,512 and US 5,750,561 are indicated as covering the composition. The Examiner might note that the 5,698,582 patent is the Bastart reference of record and discussed in Applicants' Amendment filed September 21, 2009. There Applicants explain that Bastart '582 discloses the addition of a surfactant to an ethanol solution of docetaxel.

Should there be any outstanding matters that need to be solved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned bellow, to conduct an interview in an effort to expedite prosecution in the connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.R.F. §§1.16 or 1.14; particularly, extension of time fees.

Dated: January 27, 2010

Respectfully submitted,

By mjNuell

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Attachment: slides presented in interview